



**Australian Government**

# **Assessment Requirements for MSL977009**

## **Validate test methods**

**Release: 1**

# Assessment Requirements for MSL977009 Validate test methods

## Modification History

Release 1. Supersedes and equivalent to MSL977005 Validate test methods. Minor changes to Performance Criteria and Knowledge Evidence for clarity.

## Performance Evidence

There must be evidence the candidate has completed the tasks outlined in the elements and performance criteria of this unit, and:

- validated at least 2 test methods using authorised protocols to ensure they are based on sound scientific principles and are fit for purpose.
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## Knowledge Evidence

There must be evidence the candidate has knowledge of:

- principles, concepts and workplace/regulatory requirements related to method validation and reporting
- calculation steps, mathematical and statistical techniques used to analyse results
- principles, procedures, characteristics, capabilities and limitations of equipment
- variables which should be validated and criteria for choice
- purposes of validation, including:
  - identification and impartial resolution of ethical issues, such as conflict of interest
  - ethical decision making
  - provision of products and services which match the operational and financial needs of stakeholders, including realistic quotes for work
  - accurate representation of skills, services, knowledge and qualifications of individuals and the organisation
  - acknowledgment of services and products developed by others, intellectual property (IP) and copyright
  - provision of unbiased, accurate and appropriately qualified information results
- validation protocols, including:
  - checks that are considered to ensure performance characteristics of test method are scientifically sound
  - checks, including:
    - selectivity
    - linearity
    - range
    - sensitivity and specificity
    - limit of detection

- limit of quantitation
- accuracy
- precision
- recovery
- ruggedness
- carryover
- assessment of the clarity and completeness of the description of the method
- legal, ethical, and work health and safety (WHS) requirements specific to the work task.
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## Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions and contingencies. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
  - a standard laboratory equipped with appropriate equipment, instruments, reagents and samples
  - validation protocols and workplace procedures, including test methods.

Assessors must satisfy the NVR/AQTF mandatory competency requirements for assessors.

## Links

MSL Laboratory Operations Companion Volume Implementation Guide is available from VETNet – -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>